510(K) SUMMARY K131361

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Substantial Equivalence for the use of the WarmTouch Surgical Access & Torso Blankets.

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	July 26, 2013
Contact Person:	Kelsey Lee Senior Regulatory Affairs Specialist (303) 305-2760
Proprietary Name:	**WarmTouch Surgical Access & Torso Blankets**
Common Name:	Thermal Regulation System
Device Classification Regulation:	21 CFR 870.5900 – Class II
Device Product Code & Panel:	DWJ
Predicate Device:	**WarmTouch CareDrape Cardiac Blanket (K014121)**

JUL 29 2013

Device Description

The WarmTouch Surgical Access Blanket is a sterile full body blanket with a rectangular opening that allows access to the abdominal or lower back. This blanket stays in place via medial tape.

The WarmTouch Torso Blanket is a non-sterile blanket that is intended to cover the patient from the shoulders to the waist/hips. This blanket has flaps on either side that are tucked underneath the patient and medical tape at the distal end.

These blankets are intended to be used with the WarmTouch convective warming units.

Indications for Use/Intended Use
The WarmTouch Surgical Access Blanket is indicated for use during abdominal, laparotomy, and spinal procedures. The Surgical Access Blanket is to be used only with WarmTouch convective warming units with model numbers 5015300A, 5015800, 5015900 and 5016000. The warming system is for use only in a hospital or clinical environment, and only by trained and licensed caregivers.

The WarmTouch Torso Blanket is indicated for use during procedures performed on the lower part of the body or lower extremities. The Torso Blanket is to be used only with WarmTouch convective warming units with model numbers 5015300A, 5015800, 5015900 and 5016000. The warming system is for use only in a hospital or clinical environment, and only by trained and licensed caregivers.

Technological Characteristics Comparison
The subject WarmTouch blankets have similar materials, manufacturing processes, incorporation of a medical grade tape, and the Surgical Access Blanket has an equivalent sterilization method and shelf life as the predicate CareDrape Cardiac Blanket.

The subject WarmTouch blankets have the following new features when compared to the predicate CareDrape Cardiac Blanket:

Surgical Access: label identifying orientation, a face shield, a rectangular access window, different tabs and physical dimensions

Torso: label identifying orientation, a face shield, different tabs and physical dimensions
These new technological and labelling features are not expected to raise new questions of safety or efficacy or be not substantially equivalent since the labeling change adds clarity to insure more effective use. The different physical dimensions face shield, tabs and access window have been shown to be substantially equivalent through performance and usability testing and a risk analysis has been performed for these products.

Substantial Equivalence – Non-Clinical Evidence
Substantial equivalence was shown through the following verification and validation testing:

	Modification from Predicate	Verification/Validation Test	Results
Surgical Access Blanket	New blanket design	Contact Surface Temperature	Pass
	New blanket design and construction	Useful Life	Pass
	New blanket design	Usability	Pass
	New blanket design	Anthropomorphic Design	Pass
	New material and design	Cleanliness & Sterilization	No Impact
Torso Blanket	New blanket design	Contact Surface Temperature	Pass
	New blanket design and construction	Useful Life	Pass
	New blanket design	Usability	Pass
	New blanket design	Anthropomorphic Design	Pass
Surgical Access & Torso Blanket	New blanket design, construction and materials	System Usability	Pass
	New materials	Biocompatibility	No Impact
	New blanket design	Design Validation	Pass

The results of the tests show that the subject WarmTouch Surgical Access & Torso Blankets can be considered substantially equivalent to the legally marketed predicate.

Substantial Equivalence – Clinical Evidence
N/A – Clinical evidence was not necessary to show substantial equivalence

Substantial Equivalence – Conclusions
Substantial equivalence to the predicate is shown through usability, useful life testing, anthropomorphic verification, and contact surface temperature verification. From the evidence presented in the Premarket Notification, the subject devices can be considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 29, 2013

Covidien
Ms. Kelsey Lee
Sr. Regulatory Affairs Specialist
6135 Gunbarrel Ave.
Boulder, CO 80301

Re: K131361
Trade/Device Name: WarmTouch Surgical Access & Torso Blankets
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 3, 2013
Received: June 4, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131361

Device Name: WarmTouch™ Surgical Access Blanket

Indications for Use:

The WarmTouch™ Surgical Access Blanket is intended for prevention and treatment of hypothermia, and for the management of appropriate normothermia. The warming system is for use only in a hospital or clinical environment, and only by trained and licensed caregivers.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Indications for Use

510(k) Number: K131361

Device Name: WarmTouch™ Torso Blanket

Indications for Use:

The WarmTouch™ Torso Blanket is intended for prevention and treatment of hypothermia, and for the management of appropriate normothermia. The warming system is for use only in a hospital or clinical environment, and only by trained and licensed caregivers.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)